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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,471	02/11/2004	Rafail Zubok	532/2x7 (F-280 Cont VI)	4066

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,471	ZUBOK ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Buttner-Janz (USPN 5,556,431). Referring to claims 1, 15, and 16, Buttner-Janz discloses an apparatus for replacing at least a portion of an intervertebral disc in a spinal column (fig.1, 2), comprising a first member/means (1) having a first vertebral contact surface (6) for engagement with an endplate of a first vertebral bone in the spinal column and a first articulation means (surface 4), and a second member/means (2) having a second vertebral contact surface (6) for engagement with an endplate of a second vertebral bone in the spinal column and a second articulation means (surface 4), wherein an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones, and the first and second members/means (1, 2) or articulation means (4) are operable to articulate *relative* to one another (members 1, 2, articulate relative to one another by piece 3), when disposed in the intervertebral disc space, about at least one of a first center of rotation for at least one of flexion and extension that is located outside the intervertebral disc space (the center of rotation of member 2 will be above the disc space), and a second center of rotation for lateral bending that is located outside the intervertebral disc space (the center of rotation of member 1 will be located below the disc space).

Referring to claim 2, Buttner-Janz discloses the first center of rotation located in one direction (above) and the second center of rotation located in an opposite direction (below).

Claims 1-16 are rejected under 35 U.S.C 102(b) as being anticipated by Shelokov (USPN 6,039,763). Referring to claims 1, 15, and 16, Shelokov discloses an apparatus for replacing at least a portion of an intervertebral disc in a spinal column, comprising a first member/means (1) having a first vertebral contact surface (2) for engagement with an endplate of a first vertebral bone in the spinal column and a first articulation means (3), and a second member/means (10) having a second vertebral contact surface (11) for engagement with an endplate of a second vertebral bone in the spinal column and a second articulation means (12), wherein an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones, and the first and second members/means (1, 10) or articulation means (3, 12) are operable to articulate relative to one another, when disposed in the intervertebral disc space (fig.7), about at least one of a first center of rotation (23) for at least one of flexion and extension that is located outside the intervertebral disc space (fig.3a, 3b show center of rotation above disc space), and a second center of rotation for lateral bending that is located outside the intervertebral disc space (center of rotation in fig.4a, 4b, for the convex arc in the bottom element and concave arc of the top element, will be below the disc space).

Referring to claim 2, Shelokov discloses the first center of rotation (23) located in one direction (above, seen in fig.3a, 3b) and the second center of rotation located in an opposite direction (below, see fig.4a, 4b, wherein the center of rotation of the convex arc in the bottom element and concave arc of the top element, will be below the disc space).

Referring to claim 3, Shelokov discloses a first (3) and second (12) articulation surface, which are sized and shaped to engage one another, enabling at least one of flexion, extension, and lateral bending (see fig.3a-3b, 4a-4b; col.4, lines 13-16).

Referring to claim 4, Shelokov discloses a first articulation surface (3) defined by a concave arc (from point 4 to point 5 in fig.1b), generally of radius A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (arc of 3 seen in fig.1a), generally of radius B about a first axis substantially perpendicular to a lateral plane of the spinal column, the second articulation surface (12) is defined by a convex arc (arc 12 in fig.2b), generally of radius C about a second axis substantially perpendicular to the

anterior-posterior plane of the spinal column, and a concave arc (arc 12 in fig.2a), generally of radius D about a second axis substantially perpendicular to the lateral plane of the spinal column.

Referring to claims 5-10, Shelokov discloses concave arc's greater than the convex arc's (col.3, lines 66-67; col.8, lines 38-42) to permit rotation of the vertebral bones relative one another through a range of angles, preferably about plus/minus three degrees (col.5, lines 47-52). Shelokov discloses the articulation surfaces sized and shaped to achieve substantial point-to-point contact relative to one another when the spinal column is in flexion, extension, lateral bending, and/or axial rotation (fig.3a-4b; col.4, lines 13-16).

Referring to claim11, Shelokov discloses the articulation surfaces sized and shaped to displace the vertebral bones away from one another at axial rotations outside the range of angles (see figures).

Referring to claims 12 and 13, Shelokov discloses first and second axes perpendicular to the anterior-posterior plane of the spinal column are substantially coaxial; and the first and second axes perpendicular to the lateral plane of the spinal column are substantially coaxial and Shelokov discloses the first and second axes perpendicular to the anterior-posterior plane for the spinal column lie in a plane that is substantially perpendicular to the anterior-posterior plane and the first and second axes perpendicular to the lateral plane of the spinal column lie in a plane that is substantially perpendicular to the lateral plane (see fig.3a-4b, 7).

Referring to claim 14, Shelokov discloses first (3) and second (12) articulation surfaces being saddle shaped (fig.1c, 2c) and operable to engage each other when disposed in the disc space to articulate in flexion, extension, and lateral bending (fig.7).

Claims 1-9 and 11-16 are rejected under 35 U.S.C 102(e) as being anticipated by Ferree et al. (US 2004/0024462 A1). Referring to claims 1, 15, and 16, Ferree discloses an apparatus for replacing at least a portion of an intervertebral disc in a spinal column [0002], comprising a first member/means (top member in fig.3a-3b, 4a-4e) having a first vertebral contact surface (top surface) for engagement with an endplate of a first vertebral bone in the spinal column and a first articulation means (bottom surface), and a second member/means (bottom member in fig.3a-3b, 4a-4e) having a second vertebral contact surface (bottom surface) for engagement with an endplate of a second vertebral bone in the spinal column and a second articulation means (top

surface), wherein an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones, and the first and second members/means or articulation means are operable to articulate relative to one another (see figures), when disposed in the intervertebral disc space, about at least one of a first center of rotation for at least one of flexion and extension that is located outside the intervertebral disc space (center of rotation in fig.3a is below the disc space), and a second center of rotation for lateral bending that is located outside the intervertebral disc space (center of rotation in fig.3b is above the disc space).

Referring to claim 2, Ferree discloses the first center of rotation located in one direction (below) and the second center of rotation located in an opposite direction (above).

Referring to claim 3, Ferree discloses a first and second articulation surface, which are sized and shaped to engage one another, enabling at least one of flexion, extension, and lateral bending [0007, 0024].

Referring to claim 4, Ferree discloses a first articulation surface (bottom surface of top member in figures) defined by a concave arc (fig.3b, 4a), generally of radius A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc (fig.3a, 4d, 4e), generally of radius B about a first axis substantially perpendicular to a lateral plane of the spinal column, the second articulation surface (top surface of bottom member in figures) is defined by a convex arc (fig.3b, 4a), generally of radius C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc (fig.3a, 4d, 4e), generally of radius D about a second axis substantially perpendicular to the lateral plane of the spinal column.

Referring to claims 5-9, Ferree discloses concave arc's greater than the convex arc's to permit rotation of the vertebral bones relative one another through a range of angles (a limited amount of rotation is disclosed to occur [0007], therefore, in order to rotate and articulate, inherently the concave arc's are larger than the convex arc's). Ferree discloses the articulation surfaces sized and shaped to achieve substantial point-to-point contact relative to one another when the spinal column is in flexion, extension, lateral bending, and/or axial rotation [0007, 0024].

Referring to claim11, Ferree discloses the articulation surfaces sized and shaped to displace the vertebral bones away from one another at axial rotations outside the range of angles (inherently will occur, see figures for size/shape).

Referring to claims 12 and 13, Ferree discloses first and second axes perpendicular to the anterior-posterior plane of the spinal column are substantially coaxial; and the first and second axes perpendicular to the lateral plane of the spinal column are substantially coaxial and Ferree discloses the first and second axes perpendicular to the anterior-posterior plane for the spinal column lie in a plane that is substantially perpendicular to the anterior-posterior plane and the first and second axes perpendicular to the lateral plane of the spinal column lie in a plane that is substantially perpendicular to the lateral plane (see figures).

Referring to claim 14, Ferree discloses first and second articulation surfaces being saddle shaped and operable to engage each other when disposed in the disc space to articulate in flexion, extension, and lateral bending [0007, 0024].

Claims 1-9 and 11-16 are rejected under 35 U.S.C 102 (e) as being anticipated by Ferree (USPN 6,706,068 B2). Referring to claims 1, 15, and 16, Ferree discloses an apparatus for replacing at least a portion of an intervertebral disc in a spinal column (col.1, lines 11-14), comprising a first member/means (top member in all figures) having a first vertebral contact surface (top surface) for engagement with an endplate of a first vertebral bone in the spinal column and a first articulation means (bottom surface), and a second member/means (bottom member in all figures) having a second vertebral contact surface (bottom surface) for engagement with an endplate of a second vertebral bone in the spinal column and a second articulation means (top surface), wherein an intervertebral disc space is defined substantially between the first and second endplates of the first and second vertebral bones, and the first and second members/means or articulation means are operable to articulate relative to one another, when disposed in the intervertebral disc space, about at least one of a first center of rotation for at least one of flexion and extension that is located outside the intervertebral disc space, and a second center of rotation for lateral bending that is located outside the intervertebral disc space (col.2, lines 3-8; col.4, line 61-col.5, line 12).

Referring to claim 2, Ferree discloses the first center of rotation located in one direction and the second center of rotation located in an opposite direction (col.4 line 61-col.5 line 12).

Referring to claim 3, Ferree discloses a first and second articulation surface, which are sized and shaped to engage one another, enabling at least one of flexion, extension, and lateral bending (col.3, lines 7-20).

Referring to claim 4, Ferree discloses a first articulation surface defined by a concave arc, generally of radius A about a first axis substantially perpendicular to an anterior-posterior plane of the spinal column, and a convex arc, generally of radius B about a first axis substantially perpendicular to a lateral plane of the spinal column, the second articulation surface is defined by a convex arc, generally of radius C about a second axis substantially perpendicular to the anterior-posterior plane of the spinal column, and a concave arc, generally of radius D about a second axis substantially perpendicular to the lateral plane of the spinal column (see figures 1-6 and 11a-11b).

Referring to claims 5-9, Ferree discloses concave arc's greater than the convex arc's to permit rotation of the vertebral bones relative one another through a range of angles (col.4, lines 1-10, 35-38). Ferree discloses the articulation surfaces sized and shaped to achieve substantial point-to-point contact relative to one another when the spinal column is in flexion, extension, lateral bending, and/or axial rotation.

Referring to claim11, Ferree discloses the articulation surfaces sized and shaped to displace the vertebral bones away from one another at axial rotations outside the range of angles (col.4, lines 1-10, 35-38).

Referring to claims 12 and 13, Ferree discloses first and second axes perpendicular to the anterior-posterior plane of the spinal column are substantially coaxial; and the first and second axes perpendicular to the lateral plane of the spinal column are substantially coaxial and Ferree discloses the first and second axes perpendicular to the anterior-posterior plane for the spinal column lie in a plane that is substantially perpendicular to the anterior-posterior plane and the first and second axes perpendicular to the lateral plane of the spinal column lie in a plane that is substantially perpendicular to the lateral plane (see figures).

Referring to claim 14, Ferree discloses first and second articulation surfaces being saddle shaped (see fig.6a, 6b) and operable to engage each other when disposed in the disc space to articulate in flexion, extension, and lateral bending.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER